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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,183	09/18/2006	Hiroko Inomata	0649-1340PUS1	8800

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EXAMINER

WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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04/02/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/593,183	Applicant(s) INOMATA ET AL.	
	Examiner Ethan Whisenant	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-20, 22-26 and 28-42 is/are rejected.
- 7) ☒ Claim(s) 6, 26 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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NON-FINAL ACTION

1. The applicant's response (filed) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 1-20 and 22-42** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

2. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

35 USC § 112- 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

4. **Claim(s) 2-5, 18-20, 28-33 and 42** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 and 24 are indefinite in that they recite the phrase "adsorbed by a weak interaction involving substantially no ionic bonds". This is a relative term and therefore the metes and bounds of what is intended cannot be determined. After carefully reviewing the specification it is unclear to the examiner what is intended by the phrase recited above and in Claims 3 and 24.

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As regards, chemical bonds, some are considered to be “strong” (e.g. covalent bonds and ionic bonds) while others are generally considered to be “weak” e.g. hydrogen bonds and van der Waals bonds which are specific types of ionic bonds. Please clarify what is intended.

Claim 18 is indefinite in that it recites the phrase “a pressure difference-generating apparatus” lacks proper antecedent basis in Claim 1.

Claim 19, 20 and 42 are indefinite in that they recites the phrase “a weak interaction”. This is a relative term and therefore the metes and bounds of what is intended cannot be determined. After carefully reviewing the specification it is unclear to the examiner what is intended by the phrase recited above and in Claims 19, 20 and 42. As regards, chemical bonds, some are considered to be “strong” (e.g. covalent bonds and ionic bonds) while others are generally considered to be “weak” e.g. hydrogen bonds and van der Waals bonds which are specific types of ionic bonds. Please clarify what is intended.

Claim 28 is indefinite in that the phrase “the sample solution” lacks proper antecedent basis in Claim 22.

35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

CLAIM REJECTIONS UNDER 35 USC § 102

6. Claim(s) 1-2, 7-18, 22-23, 28-41 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Ekenberg [US 6,218,531 (2001)].

Ekenberg teaches a method of selectively purifying RNA which comprises all of the limitations recited in Claims 1-2, 7-18, 22-23, 28-41. See the entire document but note especially, Column 7, beginning at about line 25 – Column 26. As regards the volume of the DNase Solution utilized, as well as, its concentration recited in Claims 1-2, see Examples 1 and 2 and note especially Column 18, lines 49-53. As regards Claim 7 and 28, see Column 14, lines 1-32. Regarding Claim 12 see Example 2, which begins in Column 17. As regards the wash solution recited in Claim 22, note first Column 15, lines 36-47. As regards the recovering solution note Column 19, lines 1-5 wherein Ekenberg teach that the elution buffer(i.e. the recovering solution) is water.

35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that

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the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim Rejections under 35 USC § 103

9. Claim(s) 3-4, 24-25 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekenberg [US 6,218,531 (2001)] in view of Mori et al. [US 2003/0170664 (2003)]

Claim 3 is drawn to an embodiment of the method of Claim 1 wherein the nucleic acid adsorbing porous membrane comprises an organic polymer to which the nucleic acid is adsorbed by a weak interaction involving substantially no ionic bond.

Ekenberg teach, as argued above, a method comprising all of the limitations of Claim 3 (i.e. Claim 1) except Ekenberg do not teach using nucleic acid adsorbing porous membrane which comprises an organic polymer to which the nucleic acid is adsorbed by a weak interaction involving substantially no ionic bond. However, Mori et al. do teach a nucleic acid adsorbing porous membrane comprises an organic polymer to which nucleic acid is adsorbed by a weak interaction involving substantially no ionic bond, see at least the abstract. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ekenberg wherein the filters of Mori et al. are used in place of the filters taught by Ekenberg. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine

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arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Claim 4 is drawn to an embodiment of the method of Claim 1 wherein the nucleic acid adsorbing porous membrane comprises a hydroxyl group.

Mori et al. teach this limitation, see paragraph [0031].

Claim 24 is drawn to an embodiment of the method of Claim 22 wherein the nucleic acid adsorbing porous membrane comprises an organic polymer to which the nucleic acid is adsorbed by a weak interaction involving substantially no ionic bond.

Ekenberg teach, as argued above, a method comprising all of the limitations of Claim 24 (i.e. Claim 22) except Ekenberg do not teach using nucleic acid adsorbing porous membrane which comprises an organic polymer to which the nucleic acid is adsorbed by a weak interaction involving substantially no ionic bond. However, Mori et al. do teach a nucleic acid adsorbing porous membrane comprises an organic polymer to which nucleic acid is adsorbed by a weak interaction involving substantially no ionic bond, see at least the abstract. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ekenberg wherein the filters of Mori et al. are used in place of the filters taught by Ekenberg. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

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Claim 25 is drawn to an embodiment of the method of Claim 22 wherein the nucleic acid adsorbing porous membrane is a porous membrane comprises an organic polymer having a hydroxyl group.

Mori et al. teach this limitation, see paragraph [0031].

10. Claim(s) 19 and 42 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekenberg [US 6,218,531 (2001)] in view of the Stratagene Catalog [p.39 (1988)] and Mori et al. [US 2003/0170664 (2003)]

Claims 19 and 421 are drawn to kits.

Ekenberg teach a method which utilizes all of the reagents recited in Claims 19 and 42. Ekenberg do not teach explicitly teach placing the reagent/apparati described therein into a kit format. However Ekenberg does make clear that kits comprising the reagents and apparati necessary to perform methods in molecular biology were well known at the time of the invention as was the advantages of kits, as evidenced by the Stratagene Catalog which teaches the advantages of kits. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ekenberg wherein all of reagents and apparati necessary to perform the method of Ekenberg are assembled into a kit. The ordinary artisan would have been motivated to make this modification of Ekenberg in order to gain the advantages inherent to kits. It is noted that Ekenberg do not teach using a nucleic acid-adsorbing porous membrane comprising an organic polymer to which nucleic acid is adsorbed by a weak interaction, however, as argued above, Mori et al. do teach a nucleic acid-adsorbing porous membrane comprises an organic polymer to which nucleic acid is adsorbed by a weak interaction. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ekenberg wherein the filters of Mori et al. are used in place of the filters taught by Ekenberg. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie*

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obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

CLAIM REJECTIONS UNDER 35 USC § 102/103

6. **Claim(s) 20** is/are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mori et al. [US 2003/0170664 (2003)]

Claim 20 is drawn to an automated apparatus for the selective separation and purification of RNA from a mixture solution containing DNA and RNA.

Mori et al. teach an automated apparatus comprising all of the structural limitations of Claims 20, see, for example, the claims of Mori et al., Admittedly, Mori et al. do not teach using their apparatus for the selective separation and purification of RNA from a mixture solution containing DNA and RNA. However, this limitation is directed towards the intended use of the apparatus and therefore does not limit the claimed invention. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

CLAIM OBJECTIONS

11. Claim(s) 6, 26-27 is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

ALLOWABLE SUBJECT MATTER

12. Claim(s) 5 would appear to be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action.

DUPLICATE CLAIMS -WARNING

13. Applicant is advised that should claim 19 be found allowable, claim 42 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

CONCLUSION

14. Claim(s) 1-20 and 22-42 is/are rejected and/or objected to for the reason(s) set forth above.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634

EXAMINER SEARCH NOTES

20 MAR 09 - ECW

Databases searched: USPATFULL, USPG-PUBS, JAPIO and EUROPATFULL via EAST &

CAplus, Medline and BIOSIS via STN

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

Inventor(s) : e.g. Inomata H?/au

Cartridge or column

Silica

Isolation or extraction

DNA or RNA or nucleic

DNase

DeFoam\$ or antifoam

Acetyl celluloses

Chaotropic salt or guanidine

Organic or cellulose or nitrocellulose same filter\$